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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,682	04/13/2004	Eric Berreklouw	2001-1105-1	2986
<div>465 7590 08/29/2008</div> <div>YOUNG & THOMPSON 209 Madison Street Suite 500 ALEXANDRIA, VA 22314</div>				
EXAMINER				
BLANCO, JAVIER G				
ART UNIT		PAPER NUMBER		
3774				
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08/29/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/822,682

Applicant(s)

BERREKLOUW, ERIC

Examiner

JAVIER G. BLANCO

Art Unit

3774

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 108223 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 72-83, 85-90 and 122-128 is/are pending in the application.
- 4a) Of the above claim(s) 76, 78-83, 85-87, 89 and 90 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 72-75, 77, 88, and 122-128 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. Applicant's amendment of claims 72-83 and 85-89 in the reply filed on April 30, 2008 is acknowledged.
2. Applicant's addition of claims 125-128 in the reply filed on April 30, 2008 is acknowledged.

Claim Objections

3. The claims are objected to because of the following informalities:
 - a. Regarding each instance of "fixing position", please substitute with ~~--fixing~~ **implanted** position--. Appropriate correction is required.
 - b. Regarding claim 128, please substitute "Claim 72" with ~~--Claim 72~~ **125**--. Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (c) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 72-75, 77, 88, 123-125, and 128 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by **Shiley** (US 3,686,740 A; cited in Applicant's IDS).

Referring to Figures 5-7, 9, 13, 14, and 25-30, Shiley discloses a prosthesis fixing device comprising a tubular element (**first interpretation:** Figure 5-7: outer ring 11; Figures 13 and 14: outer ring 111; **second interpretation:** outer ring + inner ring) providing a lumen (**first interpretation:** lumen formed by outer ring; **second interpretation:** lumen formed between the outer ring and the inner ring) therethrough and *intended to lie*, when the prosthesis fixing device is in an inserted position, with an outside in contact (directly or indirectly) with a wall part of the circulatory system and capable of accommodating a valve prosthesis (e.g., valve 15) inside the lumen of said tubular element, the tubular element having pins (pins 13) distributed around the periphery of said tubular element, said pins having pointed ends, wherein each pin is arranged on an arm which arm, via a fold or bend line, is fixed (e.g., when valve prosthesis is assembled) by one end to the tubular element (also see Figure 13), wherein the arms and pins are capable of moving, by swinging about the fold or bend line, from an insertion position (e.g., Figure 5), in which they are **ESSENTIALLY** located inside the lumen of the tubular element, to a fixing position (e.g., Figure 6) in which at least the pins project from the outside of the tubular element. Each of wire suture pins 13 comprises a basal end 43, a body portion 50, and a distal end 49. The tubular element is provided with slit-shaped radial passages (e.g., radial slots 35, annulus 52, and/or apertures 41) located alongside the pins in the radial direction, which slit-shaped radial passages extend in the longitudinal direction (e.g., pointing in the same direction) of the arms. Regarding the term “integral”, it is broadly interpreted as “unitary”. “Integral” is not the same as “monolithic”.

The valve prosthesis comprising a cylindrical outer body (**first interpretation:** outer surface of the valve prosthesis; **second interpretation:** inner ring 12, inner ring 112; **third interpretation:** outer surface of valve prosthesis + inner ring, as an assembly) fitting in the lumen of said tubular element. Regarding the “bend line”, both of Figures 5 and 6 (see also Figures 26 and 27) clearly show the arms and pins as movable about a bend line. It is noted that the pins are not straight, but have a curve/bend profile. The motion/movement depicted in Figures 5 and 6 could be broadly considered “by swinging”. Additionally, the swinging motion could also develop at the bend line between distal end 49 and body portion 50 (see Figure 7).

Note: Regarding the statements of intended use and other functional statements (e.g., intended to lie; to accommodate; permits swinging; etc.), they do not impose any structural limitations on the claims distinguishable over the device of Shiley ‘740, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959). “[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

6. Claims 72-75, 77, 88, and 122-128 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by **Stevens** (US 5,370,685 A; cited in Applicant’s IDS).

Referring to Figures 9-15, Stevens discloses a prosthesis fixing device comprising a tubular element (annular ring 85) providing a lumen (lumen of ring 85) therethrough and *intended to lie*, when the prosthesis fixing device is in an inserted position, with an outside in contact (directly or indirectly) with a wall part of the circulatory system and capable of accommodating a valve prosthesis (see Figure 11) inside the lumen of said tubular element, the tubular element having pins (mounting pins 90) distributed around the periphery of said tubular element, said pins having pointed ends (Figures 13a-15b), wherein each pin is arranged on an arm (**first interpretation:** main body portion of mounting pins 90; **second interpretation:** half the body portion of mounting pin 90) which arm, via a fold or bend line (Figures 13b, 14b, 15a, and 15b), is fixed by one end to the tubular element, wherein the arms and pins are capable of moving, by swinging about the fold or bend line (compare Figure 10 to Figure 11; compare Figure 13b to Figure 14b; compare Figure 15a to Figure 15b; see column 9, lines 35-47), from an insertion position, in which they are ESSENTIALLY located inside the lumen of the tubular element (compare Figure 10 to Figure 11; compare Figure 13b to Figure 14b; compare Figure 15a to Figure 15b; see column 9, lines 35-47), to a fixing position in which at least the pins project from the outside of the tubular element. The tubular element is provided with slit-shaped radial passages (see Figure 13a and Figure 14a) located alongside the pins in the radial direction, which slit-shaped radial passages extend in the longitudinal direction (e.g., pointing in the same direction) of the arms. The valve prosthesis comprising a cylindrical outer body fitting in the lumen of said tubular element. Regarding the term “integral”, it is broadly interpreted as “unitary”. “Integral” is not the same as “monolithic”.

With regards to statements of intended use and other functional statements (e.g., intended to lie; to accommodate; permits swinging; etc.), they do not impose any structural limitations on the claims distinguishable over the device of **Stevens**, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959). “[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

Response to Arguments

7. With regards to the 102(b) rejection based on **Shiley** (US 3,686,740 A; cited in Applicant’s IDS), Applicant’s arguments filed April 30, 2008 have been fully considered but they are not persuasive.

a. The Applicant argues that Shiley does not disclose the arm as “*is fixed by one end to the tubular element*”. The Examiner respectfully disagrees. Under the lumen “first interpretation” and “second interpretation” provided by the Examiner, an end (e.g., basal half or basal third of wire suture pins 13) is fixed (e.g., when valve prosthesis is assembled) to the tubular element. Further, Figure 13 clearly shows the subject matter of an end fixed to the tubular element (e.g., outer ring).

b. The Applicant argues that Shiley does not disclose the arms and pins *"from an insertion position, in which they are essentially located inside the lumen of the tubular element"*. The Examiner respectfully disagrees. Under the several "lumen" interpretations offered by the Examiner (see 102(b) rejection above), pins 13 are essentially located inside the lumen (**first interpretation:** lumen formed by outer ring; **second interpretation:** lumen formed between the outer ring and the inner ring) of the tubular element in the insertion position. Said lumen is provided through the tubular element (e.g., before and/or after final assembling).

c. Regarding limitation *"the valve prosthesis comprising a cylindrical outer body fitting in the lumen of said tubular element"*, the "cylindrical outer body" is broadly interpreted as either the outer surface of the valve prosthesis; inner ring 12 (or inner ring 112); or outer surface of valve prosthesis + inner ring, as an assembly. The Figures clearly show said "cylindrical outer body" as "fitting in the lumen of said tubular element".

d. Regarding claim 73 and claim 128, the tubular element (**first interpretation:** Figure 5-7: outer ring 11; Figures 13 and 14: outer ring 111; **second interpretation:** outer ring + inner ring) is provided with slit-shaped radial passages (e.g., radial slots 35, annulus 52, and/or apertures 41) wherein the pins emerge through these passages (e.g., radial slots 35) and the arms (e.g., basal half or basal third of wire suture pins 13) are located within the passages (e.g., annulus 52 and/or apertures 41).

e. Regarding claim 74, Figure 7 clearly shows a portion of the arm as extending essentially in the longitudinal direction of the tubular element. Regarding claim 75, Figure 7 clearly shows another portion of the arm as extending in tangential direction of the tubular element.

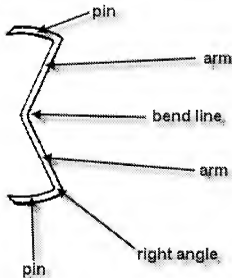
- f. Regarding claim 77, in the insertion position the arms viewed from the bend line point away from the outside of the tubular element (e.g., the arms are not outside of the tubular element).
- g. Regarding claim 88, no structure has been claimed in said claim. The entire claim only recites functional language. Said functional statements do not impose any structural limitations on the claims distinguishable over the device of **Shiley**, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959).
- h. Regarding claim 123, the term “integral”, it is broadly interpreted as “unitary”. “Integral” is not the same as “monolithic”.

8. With regards to the 102(b) rejection based on **Stevens** (US 5,370,685 A; cited in Applicant's IDS), Applicant's arguments filed April 30, 2008 have been fully considered but they are not persuasive.

- a. The Applicant argues “*STEVENS discloses pins with pointed ends, but those pins are at any time located outside the tubular element. Those pins are not located inside any lumen of the tubular element*”. The Examiner respectfully disagrees. Figures 13b and 15a clearly show mounting pins 90 as comprising a bend line, arms, and pins (pointed ends), wherein the arms are slanted (i.e., extend obliquely) backwards (i.e., towards the lumen of the tubular element).
- b. The Applicant argues “*the STEVENS' pins are not arranged on arms, but are directly fixed to the tubular element itself*”. The Examiner respectfully disagrees. Figures 13b, 14b, 15a, and 15b

clearly show mounting pins 90 as comprising a bend line, arms, and pins (pointed ends), wherein pins 90 are fixed to the tubular element (clearly disclosed at column 9, lines 35-47).

See representation of Figure 15a of Stevens '685 below:



c. Regarding claim 73, the tubular element is provided with slit-shaped radial passages (see Figure 13a and Figure 14a), viewed in radial direction of the tubular element, located alongside the pins and arms, such that, on swinging from the insertion position into the fixing position, the pins emerge through these passages and the arms are located within the passages. Contrary to Applicant's assertion (i.e., "passages are checked-shaped"), Stevens radial passages are slit-shaped.

d. Regarding claim 88, no structure has been claimed in said claim. The entire claim only recites functional language. Said functional statements do not impose any structural limitations on the claims distinguishable over the device of **Stevens**, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Claims directed to apparatus must be distinguished from the prior art in

terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959).

e. Regarding claim 123, the term “integral”, it is broadly interpreted as “unitary”. “Integral” is not the same as “monolithic”.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

G.G. Siposs et al. (US 3,371,352): Figures 4-10

Robertson et al. (US 5,984,959 A): Figures 3-5

Berg et al. (US 7,147,663 B1): Figures 3, 5, and 11-13

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (9:00 a.m.-7:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on (571)272-4749. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Javier G. Blanco/

Examiner, Art Unit 3774

/Dave Willse/

Primary Examiner, Art Unit 3738